

REMARKS

In view of the following remarks, the Examiner is requested to allow claims 5-7, 19-22, 24-29, and 31-41, the only claims pending and under examination in this application.

Claims 1-4, 8-18, 23, and 30 were previously canceled without prejudice.

Claim Rejections – 35 U.S.C. § 101

Claims 5-7, 19-22, 24-29, and 31-41 were again rejected under 35 U.S.C. § 101 because the claimed invention is allegedly drawn to an invention with no apparent or disclosed specific and substantial credible utility. This rejection is respectfully traversed.

Initially, Applicant wishes to point out that the above rejection is procedurally flawed in that it does not comport with the § 101 Guidelines or Training Materials. First, the actual statement of the rejection (*no apparent or disclosed specific and substantial credible utility*) is contrary to the prescribed manner of making a rejection under § 101. For example, the flowchart at page 9 (Exhibit A) and the Form Paragraphs at pages 10 and 11 (Exhibit B) of the Revised Interim Utility Guidelines Training Materials state clearly either that credibility is not assessed if there is no disclosed specific and substantial utility (Rejection format “A”) or that credibility is assessed only when at least one specific and substantial utility is disclosed (Rejection format “B”).

An example of a § 101 rejection under Format A is:

Claims 1-10 are rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility. No provision is made in the flowchart or form paragraphs for a rejection phrased as in the present rejection, i.e., *no apparent or disclosed specific and substantial credible utility*. If the Examiner believes that the assertion of utility lacks a specific and substantial utility, the issue of credibility is never reached, and credibility should not be mentioned in the rejection.

An example of a § 101 rejection under Format B is:

Claims 1-10 are rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a credible asserted utility or a well-established utility. No provision is made in the flowchart or form paragraphs for a rejection phrased as in the present rejection, i.e., *no apparent or disclosed specific and substantial credible utility*. In this format, the issue of credibility is reached only when a specific

and substantial utility is disclosed or asserted. In such a situation, only credibility, and not specific and substantial utility should be mentioned, in the rejection.

There is one additional format, Format C, for situations with multiple utilities, some of which are not specific and/or substantial, and some of which are not credible, but none of which is specific, substantial, and credible.

An example of a § 101 rejection under Format C is:

Claims 1-10 are rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a specific and substantial asserted utility, a credible asserted utility, or a well-established utility. The either/or language in the sample rejection indicates that specific and substantial asserted utility is an alternative to credible asserted utility. Again, no provision is made in the flowchart or form paragraphs for a rejection phrased as in the present rejection, i.e., *no apparent or disclosed specific and substantial credible utility*.

Because the rejection is not phrased properly, Applicant requests clarification regarding the basis (specificity and substantiality OR credibility) of the rejection.

Second, the Utility Guidelines do not require factual evidence within Applicant's disclosure at the time of filing (as required by the Examiner) in support of an asserted utility. If the Examiner has reason to question the asserted utility, (s)he should cite documentary evidence whenever possible in support of the rejection. The proper applicable evidentiary standard is a preponderance of the evidence standard, i.e., a *more likely than not* or greater than a 50% chance standard. MPEP § 2107. Therefore, merely doubting an assertion of utility, without providing sufficient documentary evidence, does not satisfy this standard because mere doubting results in a 50-50 tie and does not evince that the Examiner is *more likely than not* correct. The Examiner's assertion that "significant further research would have to be conducted" (Office Action at page 4) is only an assertion or opinion. It does nothing to break the 50-50 tie.

Furthermore, the Examiner's requirement for factual evidence within Applicant's disclosure at the time of filing is improper. Later publications that substantiate Applicant's assertions of utility or other art-related facts existing on the filing date are acceptable. *In re Hogan and Banks*, 194 USPQ 527, 537 (CCPA 1977). For example, Applicant has disclosed (specification at page 5) that the Grb7 family proteins exhibit differential expression in certain human cancers (particularly breast and prostate cancer) (emphasis added). The phrase *certain human cancers* embraces the gastric and esophageal cancers disclosed by Kishi *et al.* and Tanaka *et al.*, respectively. Apparently the Examiner is requiring that a

generic statement of utility be accompanied by an exhaustive litany of specific utilities that fall within the genus in order for later published specific knowledge to substantiate Applicant's assertion of utility. The Examiner is respectfully requested to cite authority for such a requirement, which clearly places an undue burden upon an Applicant.

The Examiner has asserted "that the patent law requires that the specific and substantial credible utility of the claimed invention must be fully disclosed at the time of filing, which precludes any subsequent recitation of asserted utility of the claimed invention." Office Action at page 6. Applicant submits that the specification does include a full disclosure of utility. Kishi *et al.* and Tanaka *et al.*, for example, do not *supply* a utility statement, they properly *substantiate* Applicant's utility statement.

Finally, the Examiner asserted "that the observed overexpression of Grb14 protein in a prostate or breast cell cannot be unequivocally indicative of Grb14 being a marker for these types of cancer...." Office Action at pages 7-8 (emphasis added). Applicant is not required to prove his utility unequivocally. The burden is on the Office to substantiate any reasons for doubting an asserted utility. By citing the general Baguley *et al.* paper, once again the Examiner has not met the evidentiary standard of a preponderance of the evidence. The Daly *et al.* paper (J. Biol. Chem. (1996) 271:12502-12510) cited previously by Applicant is far more relevant to breast and prostate cancer than is the general Baguley *et al.* paper. Therefore, at best there is a 50-50 tie, Applicant's word against the Examiner's, and a tie is broken in favor of Applicant.

Therefore, Applicant submits that a both a specific and substantial utility and a credible utility are disclosed in the specification. Withdrawal of this rejection is respectfully requested.

Claim Rejections – 35 U.S.C. § 112, first paragraph

Claims 5-7, 19-22, 24-29, and 31-41 have been rejected under 35 U.S.C. §112, first paragraph, because one skilled in the art would allegedly not know how to use the claimed invention since the claimed invention is allegedly not supported by either a clearly asserted utility or a well-established utility. This rejection is respectfully traversed.

For the reasons set forth above, Applicant has in fact asserted a specific and substantial utility and a credible utility. Because this rejection is based on the premise of lack of utility, the rejection must fall. Withdrawal of this rejection is respectfully requested.

CONCLUSION

The Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the one of the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number RICE-012.

Respectfully submitted,
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Date: December 15, 2005

By: _____
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Registration No. 48,105

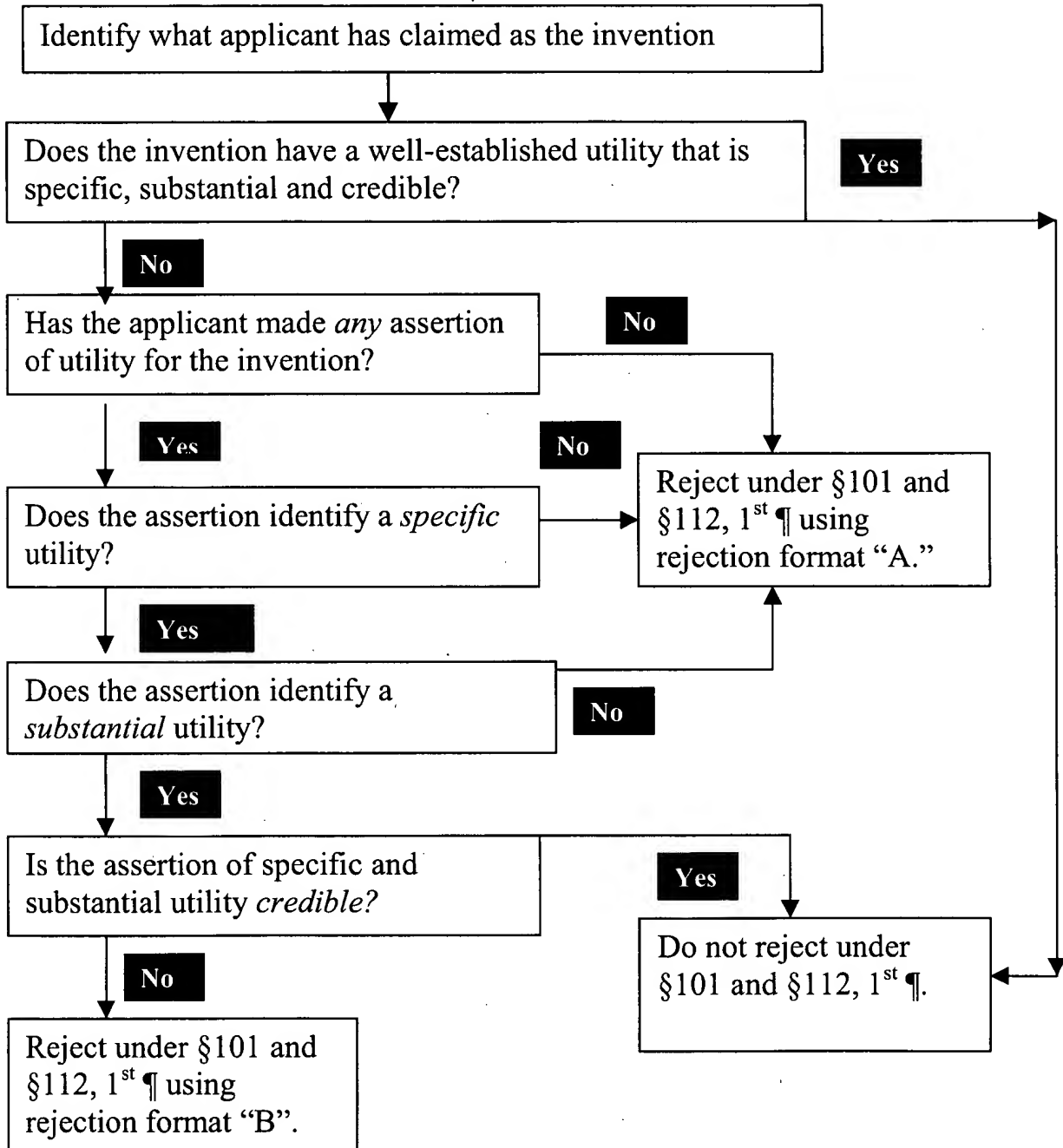
Enclosures: Exhibit A: Flowchart at page 9 of the Revised Interim Utility Guidelines Training Materials
 Exhibit B: Form Paragraphs at pages 10 and 11 of the Revised Interim Utility Guidelines Training Materials

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EXHIBIT A

Flowchart at page 9
of the
Revised Interim Guidelines
Training Materials

Utility Review Flowchart



Rejection format "A": Applicant has not disclosed any specific and substantial utility for the claimed invention, credibility will not be assessed.

Rejection format "B": Applicant has disclosed at least one specific and substantial utility for the claimed invention, but the assertion is not credible.

EXHIBIT B

Form Paragraphs at pages 10 and 11
of the
Revised Interim Utility Guidelines
Training Materials

Form Paragraph

7.05.01 - UTILITY REJECTIONS UNDER 35 U.S.C. § 101 AND 35 U.S.C. 112, FIRST PARAGRAPH

Claim [1] rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a [2] asserted utility or a well-established utility.

[3]

Claim [4] also rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by either a [5] asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention so that it would operate as intended without undue experimentation.

Format A: No specific and substantial utility

- a) Insert the same claim numbers in brackets 1 and 4.
- b) Insert "specific and substantial" in brackets 2 and 5.
- c) In bracket 3, insert the explanation as to why the claimed invention is not supported by a specific and substantial asserted utility or a well-established utility. Note in the office action that credibility will not be assessed.

d) Format A is to be used either when there is no asserted utility or when there is an asserted utility that is not specific and substantial.

Format B: No credible utility

- a) Insert the same claim numbers in brackets 1 and 4.
- b) Insert "credible" in brackets 2 and 5.
- c) In bracket 3, insert the explanation as to why the claimed invention is not supported by either a credible asserted utility or a well-established utility. Note that a utility that is inoperative is not credible.

Format C: For claims that have multiple utilities, some of which are not specific and/or substantial, and some of which are not credible, but none of which are specific, substantial and credible:

- a) Insert the same claim numbers in brackets 1 and 4.
- b) Insert "specific and substantial asserted utility, a credible" in brackets 2 and 5.
- c) In bracket 3, insert the explanation as to why the claimed invention is not supported by a specific and substantial asserted